UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MARY BAYES and PHILIP BAYES,	)	
	)	
Plaintiff(s),	)	
	)	
vs.	)	Case No. 4:13-cv-00800-SRC
	)	
BIOMET, INC., et al.,	)	
	)	
Defendant(s).	)	

Memorandum and Order

Plaintiffs and Biomet have separately filed motions in limine to limit or exclude evidence at trial. *See* Docs. 205, 241. During the pretrial conference on September 24, 2020, the Court ruled on many of the parties' motions in limine, but reserved ruling on others pending supplemental briefing. Doc. 266. The Court now considers the parties' remaining motions in limine.

I. Biomet's Motions

A. Biomet's Motion in Limine No. 5

Biomet's motion in limine No. 5 seeks to exclude evidence of risks and complications that Mary Bayes never experienced. In Missouri, future damages in a personal injury action are not compensable unless reasonably certain to occur. *Thomas v. FAG Bearings Corp. Inc.*, 846 F. Supp. 1400, 1408 (W.D. Mo. 1994). Thus, "[i]n order to recover, plaintiffs must prove that the risk of contracting [future complications] is a reasonable certainty." *Id.* "To show that a risk is a reasonable certainty, there must be evidence of a quantified risk—medical evidence must establish that an individual plaintiff will more likely than not develop [the future complication]." *Id.*; *see also Elam v. Alcolac, Inc.*, 765 S.W.2d 42, 208 (Mo. Ct. App. 1988) (expert testimony

must quantify probability as greater than fifty percent). Without citation to the record, Plaintiffs assert that Mary's physicians "have opined that she [has] an increased risk for hip dislocation procedures, hip revision procedures and all of the attendant risks involved with those." Doc. 270. On the other hand, Defendants contend that "Plaintiffs have not identified *any* medical records or admissible expert testimony to support that [Mary]…will experience these complications." Doc. 269.

On this record, the Court denies without prejudice Biomet's motion in limine No. 5. However, the Court will not permit any evidence or testimony regarding Mary's risk of future complications (or her fears regarding such risks) unless Plaintiffs first make an offer of proof supported by admissible expert testimony that Mary is more likely than not to experience the complication at issue.

B. Biomet's Motion in Limine No. 7

Biomet's motion in limine No. 7 seeks to exclude documents from DePuy Orthopaedics—a Biomet competitor—produced by Biomet in this case as part of the "custodial file" of a current Biomet employee, Jim Lancaster. Plaintiffs argue that the DePuy documents are relevant because DePuy manufactured a substantially similar metal-on-metal hip implant "that caused substantially similar injuries." Doc. 270 at 2. Based on the purpose for which Plaintiffs seek to offer this evidence, the Court finds this issue subsumed by its prior ruling on Biomet's motion in limine No. 1 (regarding other similar incidents). The Court will only allow evidence of other incidents upon a showing—by offer of proof outside the presence of the jury—of substantial similarity. Thus, the Court denies without prejudice Biomet's motion in limine No. 7.

II. Plaintiffs' Motions

A. Plaintiffs' Motion in Limine No. 2

Plaintiffs' Motion in Limine No. 2 seeks to exclude expert testimony by any of Plaintiff's treating physicians not disclosed under Federal Rule of Civil Procedure 26(a)(2)(a). The Rule requires "that 'a party must disclose to the other parties the identity of any witness it may use at trial to present' expert testimony." *Vanderberg v. Petco Animal Supplies Stores, Inc.*, 906 F.3d 698, 702 (8th Cir. 2018) (quoting Fed. R. Civ. Proc. 26(a)(2)). "The nature and extent of the required disclosure turns on whether or not the expert witness is 'retained or specially employed to provide expert testimony in the case.'" *Id.* Although "[t]he disclosure rule is less demanding for experts that are not specially employed or retained for litigation, such as treating physicians," a party seeking to elicit opinion testimony from a treating physician must disclose the treater's identity and disclose "the subject matter on which the witness is expected" to opine and "a summary of the facts and opinions to which the witness is expected to testify." *Id.* (quoting Fed. R. Civ. Proc. 26(a)(2)(C)).

Plaintiffs specifically seek to exclude expert testimony from Dr. David Lewallen, arguing that Biomet did not disclose his identity or a summary of his opinions as required by Rule 26(a)(2)(C). Biomet contends that its disclosure was adequate. Biomet's expert disclosure did not identify Dr. Lewallen by name, but purported to disclose "any and all of Plaintiff's treating physicians and other healthcare providers who may testify [regarding] Plaintiff's physical condition prior to, during and subsequent to the dates of treatment at issue in this matter." Doc. 254-1. Rather than a summary of Dr. Lewallen's opinions, Biomet's expert disclosure only stated that the "testimony which may be offered by each of these healthcare providers is contained or based upon the medical records, reports, and evaluations associated with this case in

addition to the medical history of the Plaintiff." *Id.* Biomet argues that this disclosure was adequate because it previously identified Lewallen by name as one of Plaintiff's healthcare providers in its Rule 26(a)(1) initial disclosures and because Lewallen consulted with Plaintiff only once generating just a two-page visit note.

The Court finds Biomet's expert disclosure inadequate. Courts both in and outside this circuit have consistently found that generic reference to medical records does not satisfy Rule 26(a)(2)(C)'s requirement of disclosure of a summary of a treater's opinions. *See, e.g.*, *Schultz v. Ability Ins. Co.*, No. C11-1020, 2012 WL 5285777, at *5 (N.D. Iowa Oct. 25, 2012) ("reference to the medical records, without more, does not satisfy the disclosure requirement of Rule 26(a)(2)(C)"); *Brown v. Providence Med. Ctr.*, No. 8:10CV230, 2011 WL 4498824, at *1 (D. Neb. Sept. 27, 2011) ("The court will not place the burden on Defendants to sift through medical records in an attempt to figure out what each expert may testify to."); *Reynolds v. Knox Cty. Gov't*, No. 3:17-CV-79-HSM-DCP, 2018 WL 6523439, at *5 (E.D. Tenn. Dec. 12, 2018) ("Simply stating that a treating physician is expected to testify consistent with his or her records does not comply with Rule 26(a)(2)(C)."); *Ballinger v. Casey's Gen. Store, Inc.*, No. 1:10-CV-1439-JMS-TAB, 2012 WL 1099823, at *4 (S.D. Ind. Mar. 29, 2012) (allowing a party to provide medical records "in lieu of a summary would invite a party to dump a litany of medical records on the opposing party").

Federal Rule of Civil Procedure 37(c)(1) provides that when a party fails to comply with the disclosure requirements in Rule 26(a), "the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." On this record, the Court finds that Biomet's failure to specifically disclose Lewallen as an expert and provide a summary of his opinions as required by

Rule 26(a)(2)(C) was harmless. Biomet identified Lewallen by name as a healthcare provider in its initial disclosures, specifically referencing his "2015 consultation" with Plaintiff. Doc. 254-2. That consultation generated Lewallen's two-page visit note. *See* Doc. 254-4 at 405. Biomet asked questions about Lewallen's visit note during at least four depositions in this case. Docs. 254-5; 254-6; 254-7; 254-8. Despite this, *neither* party sought to depose Lewallen before the close of discovery. Doc. 192. Biomet also referenced Lewallen's note in its motion for summary judgment. Doc. 148 at ¶ 73-77. Thus, the Court finds that—despite Biomet's improper disclosure—Plaintiffs cannot claim surprise at Biomet's intention to call Lewallen to testify regarding opinions expressed in his visit note. Accordingly, the Court denies Plaintiff's motion in limine No. 2. The Court will permit Lewallen to testify regarding his treatment of Mary and the opinions expressed in his visit note.

B. Plaintiffs' Motion in Limine No. 10

Plaintiffs' motion in limine No. 10 seeks to preclude Biomet from offering any evidence or argument "that the FDA clearance of the M2a-Magnum indicates that the FDA believed" the device was safe for use. Doc. 242 at 13-14. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 480 (1996), the Supreme Court noted that an FDA finding of "substantial equivale[nce]," and clearance of a medical device for the market through the § 510(k) process, "should not be construed" as an FDA endorsement of the device's safety. *Id.* In fact, the FDA advises device manufacturers that it is "inappropriate to say" that a 510(k)-cleared device has been FDA approved, because "[o]nly products or devices approved through the premarket approval process are considered FDA approved."[1] Accordingly, the Court grants Plaintiffs' motion in limine No. 10. The Court will not permit Biomet to offer evidence or argument that the FDA's 510(k)

[1] *See* https://www.fda.gov/training-and-continuing-education/cdrh-learn/510k-program-transcript.

clearance of the M2a-Magnum constituted an endorsement of the device's safety or "FDA approval."

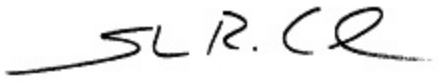
Further, the Court will not permit either party to make *any* reference to the FDA clearance/approval process or requirements. The parties do not dispute that the M2a-Magnum was legally on the market. Where a medical device, such as the M2a-Magnum, is substantially equivalent to a device already on the market, the manufacturer has no discretion to use the premarket approval process.

> Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval application (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements….[2]

See also Doc. 263-1 (Affidavit of Hollace Rhodes) at ¶ 7-13. Because 510(k) clearance does not constitute an FDA-endorsement of safety, and because Biomet had no discretion in choosing the 510(k) path, the Court finds that the FDA clearance/approval process is not relevant to any issue in the case. *See* Fed. R. Evid. 401. The Court further finds that even if it were relevant, the probative value of evidence relating to the same is "substantially outweighed by a danger of…unfair prejudice, confusing the issues, [or] misleading the jury[.]" Fed. R. Evid. 403; *cf.* Fed. R. Evid. 611. Therefore, the Court excludes any argument, comment, or reference to the FDA clearance/approval process or requirements in this case. However, the Court will permit Plaintiffs to offer evidence regarding the M2a-Magnum's 510(k) application as part of an offer of proof (outside the presence of the jury) of substantial similarity for purposes of other-similar-incidents evidence.

Dated: October 1, 2020.

[2] https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k



STEPHEN R. CLARK
UNITED STATES DISTRICT JUDGE